MAY 0 1 2014

SIEMENS

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: __k140818_____

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Ernest Joseph Senior Manager, Regulatory Affairs
Phone Number:	(914)-524-2431
Fax Number:	(914)-524-2101
E-mail Address:	ernest.joseph@siemens.com
Date Prepared:	March 31, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 Free T4 Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 Free T4 assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Free T4 assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name**

	IMMULITE® 2000 Total T4 Calibration Verification Material (CVM)
Predicate 510(k) No:	K133124

4. **Device Description:**

The IMMULITE® 2000 Free T4 Calibration Verification Material (CVM) contains one set of four vials each 1mL. CVM1contains a lyophilized processed human serum matrix with 1.58% sodium azide and preservative and CVM2, CVM3, and CVM4 contain various levels of lyophilized Free T4 in a processed human serum matrix with 1.58% sodium azide and preservative. CVMs are supplied frozen in a lyophilized form.

5. **Intended Use:**

Indication for Use:	See Indications for Use Statement below The IMMULITE® Free T4 Calibration Verification Material (CVM) for in vitro diagnostic use in the verification of calibration of the IMMULITE Free T4 assay on the IMMULITE 2000 systems
Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 Free T4 Calibration Verification Material (CVM) is substantially equivalent to the predicate device as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 Free T4 CVM	**Predicate Device IMMULITE 2000 Total T4 CVM**
Intended Use	The IMMULITE® Free T4 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Free T4 assay on the IMMULITE 2000 systems.	The IMMULITE® Total T4 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Total T4 assay on the IMMULITE 2000 systems
Storage	≤-20°C	Same
Stability	Stable unopened until the expiration date	Same
Levels	4	Same
Matrix	Human Serum with preservatives	Same
Use	Single Use Only	Same

	DIFFERENCES	
	Candidate Device IMMULITE 2000 Free T4 CVM	**Predicate Device IMMULITE 2000 Total T4 CVM**
Analyte	Free T4	Total T4
Form	Lyophilized	Liquid

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the candidate device.

Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 Free T4 Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The Calibration Verification Materials are stable up to 4 years when stored at -20°C prior to opening and stable for 8 hours at room (ambient) temperature (15-25°C) after reconstitution.

Stability Protocol Summary:
The CVM study protocols are run as part of the calibrator stability testing. As summarized in Table 2, the testing was run in duplicate (at the minimum) and contains time-points at which the testing was performed.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LFT4CVM1	1	1095	1280	1460
LFT4CVM2	1	1095	1280	1460
LFT4CVM3	1	1095	1280	1460
LFT4CVM4	1	1095	1280	1460

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE Free T4 requires dose value of stability CVMs to fall between ±10% of assigned dose for CVM level 2 and 3 and within ±15% of assigned dose for level 4. Part 2 review limits criteria requires dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±10% for levels 2 and 3 and 15% for level 4 then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE Free T4 CVMs are traceable to an internal material which has been gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
The IMMULITE Free T4 CVMs are 4 level materials which are a subset of 6 level Total Free T4 calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Free T4 reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The CVMs are manufactured using qualified materials and measurement procedures. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. Six levels of commercially available controls and 30 normal samples were used to validate CVM value assignments.

Expected Values/Target Values/Reference Range:
Each CVM level was tested for a total of 27 replicates; 9 runs and 3 replicates per run, 5 different reagent kit lots and 9 IMMULITE 2000 systems. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The target values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific value card. The expected assay range is 0.3 - 6 ng/dL. The target values in Table 3 can be considered as guidelines.

Table 3: Analyte Target Range Values

Analyte target levels	CVM Level	Target Mean (ng/dL)	Standard Deviation (SD)	Guideline ±2SD Range (ng/dL)	
	LFT4CVM1	0.00*	-	0.00	≤0.3
	LFT4CVM2	1.51	0.09	1.33	1.69
	LFT4CVM3	2.90	0.145	2.61	3.19
	LFT4CVM4	6.85*	0.515	5.82	7.88
Assay Range	0.3 - 6 ng/dL				

*Note: when CVMs are run by the customer, an actual value below and above the assay range will result when the customer programs the CVMs as calibration verifiers in the instrument software.
If programmed as a patient or control, then the software will give values as < or > the assay lower and upper range.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 Free T4 Calibration Verification Material is substantially equivalent to the predicate device intended for similar use. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 Free T4 Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

SIEMENS

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: ___k140818_____

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Ernest Joseph Senior Manager, Regulatory Affairs
Phone Number:	(914)-524-2431
Fax Number:	(914)-524-2101
E-mail Address:	ernest.joseph@siemens.com
Date Prepared:	March 31, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 IGF-I Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 IGF-I assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 IGF-I assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** IMMULITE 2000 HCG CVM
   Predicate 510(k) No: K133128

4. **Device Description:** The IMMULITE® 2000 IGF-I Calibration Verification Material (CVM) contains one set of four vials, 2mL (CVM1) each. CVM1 contains a processed bovine protein/buffer matrix with preservatives. CVM2, CVM3, and CVM4 contain various levels of IGF-I in a processed bovine protein/buffer matrix with preservatives. The CVMs are supplied frozen in a liquid form.

5. **Intended Use:** See Indications for Use Statement below
   Indication for Use: The IMMULITE® IGF-I Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE IGF-I assay on the IMMULITE 2000 systems

Special Conditions for

Use Statement(s): For prescription use only
Special Instrument Requirements: IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 IGF-I Calibration Verification Material (CVM) is substantially equivalent to the predicate device as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 IGF-I CVM	**Predicate Device IMMULITE 2000 HCG CVM**
Intended Use	The IMMULITE® IGF-I Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE IGF-I assay on the IMMULITE 2000 systems	The IMMULITE® HCG Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE HCG assay on the IMMULITE 2000 systems
Form	Liquid	Same
Levels	4	Same
Stability	Stable unopened until the expiration date	Same
Storage	≤-20°C	Same
Use	Single Use Only	Same

	DIFFERENCES	
	Candidate Device IMMULITE 2000 IGF-I CVM	**Predicate Device IMMULITE 2000 HCG CVM**
Analyte	IGF-I	HCG
Matrix	Bovine protein/buffer with preservatives	Human serum with preservatives

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the candidate device.

Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 IGF-I Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The Calibration Verification Materials are stable up to 2.5 years when stored at -20°C prior to opening, and for 8 hours at ambient temperature (room temperature) after opening.

Stability Protocol Summary:
The CVM study protocols are run as part of the calibrator stability testing. As summarized in Table 2, the testing was run in duplicate (at the minimum) and contains time-points at which the testing was performed.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LGFCVM1	1	365	730	912
LGFCVM2	1	365	730	912
LGFCVM3	1	365	730	912
LGFCVM4	1	365	730	912

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE IGF-I requires dose value of stability CVMs to fall between ±10% of the assigned dose. Part 2 review limits criteria require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±10% for each level then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE IGF-I CVMs are traceable to an internal material which has been gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
The IMMULITE IGF-I CVMs are 4 level materials which are a subset of 6 level IGF-I calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of IGF-I reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. The CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples and controls using the assigned CVM values. The controls must fall within their target ranges. Two levels of commercially available controls and 60 samples (10 spiked samples and 50 normal patient samples) were used to validate CVM value assignments.

Expected Values/Target Values/Reference Range:
The CVMs are manufactured using qualified materials and measurement procedures. The IGF-I CVMs were tested on 27 replicates in total comprised of 9 runs and 3 replicates per run on 7 IMMULITE 2000 systems and 3 different reagent kit lots. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. The CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples and

controls using the assigned CVM values. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected assay range is Up to 1600 ng/mL . The target values in Table 3 can be considered as guidelines.

Table 3: Analyte Target Range Levels

Analyte target levels	CVM Level	Target Mean (ng/mL)	Standard Deviation (SD)	Guideline ±2SD Range (ng/mL)	
	LGFCVM1	0.00	-	0.00	≤25.00
	LGFCVM2	34.7	2.8	29.1	40.3
	LGFCVM3	237	15.5	206	268
	LGFCVM4	1727*	86.5	1554	1900
Assay Range	Up to 1600 ng/mL				

*Note: when CVMs are run by the customer, an actual value below and above the assay range will result when the customer programs the CVMs as calibration verifiers in the instrument software.
If programmed as a patient or control, then the software will give values as < or > the assay lower and upper range.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. **Conclusion:**
The IMMULITE® 2000 IGF-I Calibration Verification Material is substantially equivalent to the predicate device intended for similar use. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 IGF-I Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

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510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: __k140818_____

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Ernest Joseph Senior Manager, Regulatory Affairs
Phone Number:	(914)-524-2431
Fax Number:	(914)-524-2101
E-mail Address:	ernest.joseph@siemens.com
Date Prepared:	March 31, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 Prolactin Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE 2000 Prolactin
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Prolactin assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** — IMMULITE® 2000 Growth Hormone Calibration Verification Material

Predicate 510(k) No: K133128

4. **Device Description:** IMMULITE® 2000 Prolactin Calibration Verification Material (CVM) contains one set of four vials, 3 mL each. CVM1 contains a lyophilized equine serum/buffer matrix with preservative. CVM2, CVM3, and CVM4 contain various levels of lyophilized prolactin in an equine serum/buffer matrix with preservative CVMs are supplied frozen in a lyophilized form.

5. **Intended Use:** See Indications for Use Statement below

Indication for Use: The IMMULITE® Prolactin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of the IMMULITE Prolactin assay on the IMMULITE 2000 systems

Special Conditions for Use Statement(s): For prescription use only

Special Instrument Requirements: IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 Prolactin Calibration Verification Material (CVM) is substantially equivalent to the predicate device, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 Prolactin CVM	**Predicate Device IMMULITE 2000 Growth Hormone CVM**
Intended Use	The IMMULITE® Prolactin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Prolactin assay on the IMMULITE 2000 systems.	The IMMULITE® Growth Hormone Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Growth Hormone assay on the IMMULITE 2000 systems
Form	Lyophilized	Same
Storage	2-8°C	Same
Stability	Stable unopened until the expiration date	Same
Levels	4	Same
Matrix	Equine Serum with preservatives	Same
Use	Single Use Only	Same

	DIFFERENCES	
	Candidate Device IMMULITE 2000 Prolactin CVM	**Predicate Device IMMULITE 2000 Growth Hormone CVM**
Analyte	Prolactin	Growth Hormone

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 Prolactin CVM to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The Calibration Verification Materials are stable up to 3 years when stored at 2-8°C prior to opening and stable for 8 hours at room (ambient) temperature (15-25°C) after reconstitution.

Stability Protocol Summary:
The CVM study protocols are run as part of the calibrator stability testing. As summarized in Table 2, the testing was run in duplicate (at the minimum) and contains time-points at which the testing was performed.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LPRCVM1	1	548	912	1095
LPRCVM2	1	548	912	1095
LPRCVM3	1	548	912	1095
LPRCVM4	1	548	912	1095

Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE Prolactin requires dose value of stability CVM to fall between ± 10% of assigned dose. Part 2 review limits criteria requires dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±10% for each level then additional data review is conducted using part 2 criteria.

Traceability:
The IMMULITE Prolactin CVMs are traceable to 3rd IS 84/500. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:
The IMMULITE® 2000 Prolactin CVMs are 4 level materials which are a subset of 8 level Prolactin calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Prolactin reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples and controls using the assigned CVM values. Six levels of commercially available controls and 30 samples (10 normal patients and 20 spiked normal patient samples) were used to validate CVM value assignments.

Expected Values/Target Values/Reference Range:
The Prolactin CVMs were tested on 27 replicates in total comprised of 9 runs and 3 replicates per run, 8 IMMULITE 2000 systems and 4 different reagent kit lots. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples and controls using the assigned CVM values. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected assay range is 0.5 - 150 ng/mL. The target values in Table 3 can be considered as guidelines.

Table 3: Analyte Target Range Levels

Analyte target levels	Level	Target Mean (ng/mL)	Standard Deviation (SD)	Guideline ±2SD Range (ng/mL)	
	LPRCVM1	0.00*	-	0.00	≤0.5
	LPRCVM2	8.55	0.725	7.10	10.0
	LPRCVM3	42.7	3.0	36.7	48.7
	LPRCVM4**	195	-	-	-
	80% LPRCVM4 + 20% LPRCVM1	156*	12.5	131	181
Assay Range	0.5 - 150 ng/mL				

*Note When CVMs are run by the customer, an actual value below and above the assay range will result when the customer programs the CVMs as calibration verifiers in the instrument software.
If programmed as a patient or control, then the software will give values as < or > the assay lower and upper range.
**Note: LPRCVM4 requires dilution to ensure the target value is within +10% of the top of the reportable range of the assay.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 Prolactin Calibration Verification Material is substantially equivalent to the predicate device intended for similar use. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 Prolactin Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2014

SIEMENS HEALTHCARE DIAGNOSTICS INC.
MR.ERNEST JOSEPH
SENIOR MANAGER, REGULATORY AFFAIRS
511 BENEDICT AVE.
TARRYTOWN NY 10591

Re: K140818
Trade/Device Name: IMMULITE® 2000 Free T4 Calibration Verification Material,
IMMULITE® 2000 IGF-1 Calibration Verification Material,
IMMULITE® 2000 Prolactin Calibration Verification Material
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: March 31, 2014
Received: April 1, 2014

Dear Mr. Ernest Joseph:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act): 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140818

Device Name
IMMULITE®2000 Free T4 Calibration Verification Material, IMMULITE®2000 IGF-1 Calibration Verification Material, and IMMULITE®2000 Prolactin Calibration Verification Material

Indications for Use *(Describe)*

The IMMULITE® Free T4 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Free T4 assay on the IMMULITE 2000 systems.

The IMMULITE® IGF-1 Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE IGF-1 assay on the IMMULITE 2000 systems.

The IMMULITE® Prolactin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Prolactin assay on the IMMULITE 2000 systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

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